

REMARKS

Claims 1-15 have been canceled without prejudice or disclaimer. Claims 16-54 have been added and therefore are pending in the present application. Claims 16-54 are supported by claims 1-15.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Restriction and Election of Species Requirements

The Office Action made restriction and election of species requirements. As provided therein, Applicants provisionally elected with traverse the invention of Group I, i.e. claims 1-9, and position 62 as the species and any one of the further modifications recited at lines 6-27 of claim 1. Applicants confirm this election. Applicants reserve the right to file continuing applications directed to non-elected subject matter.

II. The Objection to the Specification

The Office objected to the specification because claims 1, 2, and 4-9 do not have designations that describe their subject matters according to the requirements of 37 CFR 1.821.

Claims 1-9 have been rewritten as claims 16-54 to address this objection. Therefore, this objection has been overcome.

III. The Objection to Claims 1-3

The Office objected to claims 1-3 because of informalities. Claims 1-9 have been rewritten as claims 16-54 to address this objection. Therefore, this objection has been overcome.

IV. The Rejection of Claims 1-7 under 35 U.S.C. 101

Claims 1-7 are rejected under 35 U.S.C. 101 "because the claimed invention is directed to non-statutory subject matter." This rejection is respectfully traversed.

The claimed invention is drawn to protease variants, i.e., proteases having an altered amino acid sequence. Thus, the claims are not drawn to products of nature.

However, in order to advance prosecution, the newly presented claims use the term "isolated." Therefore, this rejection has been overcome.

V. The Rejection of Claims 1, 2 and 4-9 under 35 U.S.C. 112

Claims 1, 2 and 4-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

As set forth in Federal Circuit decisions, a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

The test is not whether one of ordinary skill in the art envisions all of the claimed subject matter, as suggested in the Office Action. Indeed, the Federal Circuit held that, "It is not correct ... that all functional descriptions of genetic material fail to meet the written description requirement." *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d at 1613.

The claimed invention is drawn to protease variants having protease activity, comprising specific modifications. The specification fully describes the protease variants of the present invention. Based on Applicants' disclosure, the skilled artisan would be led to make other mutations in addition to the mutations recited in the claims to obtain the benefits described in the present application. Applicants therefore submit that the specification demonstrates that Applicants had possession of the claimed invention at the time the application was filed.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. The Rejection of Claims 1, 2 and 4-7 under 35 U.S.C. 112

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 112, first paragraph, "because the specification, while being enabling for the preparation of modified subtilases having no more than ten amino acid sequence modifications at positions selected for modification numbered according to the amino acid sequence of the mature subtilisin BPN' set forth in SEQ ID NO: 2 [sic, SEQ ID NO: 1], does not reasonably provide enablement for the preparation of modified, generic proteases having as many as 149 amino acid sequence modifications at positions recited in the claims if numbered according to no particular amino acid sequence." This rejection is respectfully traversed.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 USPQ at 369.

"The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art ... The test is not quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed ..." *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).

It is also well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974). See also *U.S. v. Telectronics*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974); *Ex parte Hitzeman*, 9 U.S.P.Q.2d 1821 (BPAI 1988).

Moreover, in the absence of any evidence or apparent reason why compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. *In re Kamal*, 158 U.S.P.Q. 320 (C.C.P.A. 1968). See also *In re Stark*, 172 U.S.P.Q. 402, 406 n. 4 (C.C.P.A. 1972) (the burden is upon the Patent Office to set forth reasonable grounds in support of its contention that a claim reads on inoperable subject matter).

In the present application, the specification contains numerous working examples of modified proteases. Furthermore, the specification contains an extensive disclosure of techniques which are well known in the art and indeed routine for persons of ordinary skill in the art for identifying other protease variants of the present invention. It is well within the skill of the art to isolate and identify the claimed protease variants using the Applicants' disclosure.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

VII. The Rejection of Claims 1-9 under 35 U.S.C. 112

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 1-9 have been rewritten as claims 16-54 to address this rejection. Applicants therefore submit that this rejection has been overcome.

VIII. The Rejection of Claims 1, 4, 5, 8 and 9 under the Doctrine of Obviousness-Type Double Patenting

Claims 1 and 4 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,245,901. Claims 1, 5, 8 and 9 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 78 and 122 of U.S. Application No. 09/957,806. These rejections are respectfully traversed.

U.S. Patent No. 6,245,901 and U.S. Application No. 09/957,806 claim modified proteases. However, neither claim the protease variants of the present invention.

For the foregoing reasons, Applicants submit that the claims overcome these rejections under the doctrine of obviousness-type double patenting. Applicants respectfully request reconsideration and withdrawal of the rejections.

IX. The Rejection of Claims 1-9 under 35 U.S.C. 102

Claims 1, 4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by von der Osten et al. (U.S. Patent No. 6,245,901). Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Poulouse et al. (U.S. Patent Nos. 6,312,936, 6,482,628 and 6,927,055). Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Ghosh et al. (U.S. Patent Nos. 6,376,450, 6,610,642 and 6,838,425). Claims 1-4, 6, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Brode et al. (U.S. Patent Nos. 6,436,690, 6,455,295 and 6,475,765). Claims 1-3, 5, 6, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Brode et al. (U.S. Patent No. 6,599,730). Claims 1, 5 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Roggen et al. (U.S. Application Publication No. 2005/0181446). These rejections are respectfully traversed.

The cited references disclosed protease variants. However, none of the references disclose or suggest the protease variants claimed herein.

For the foregoing reasons, Applicants submit that the claims overcome these rejections under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejections.

X. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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